

Guidelines for Prescribing Amphetamine, Amphetamine-Like And Anorectic Controlled Substances (Schedule III & IV)

Practice standards for the prescribing of Amphetamine, Amphetamine-Like and Anorectic Controlled Substances (Schedule II) were established by 201 KAR 9:016. This regulation prohibits the use of these controlled substances (Schedule II) for the treatment of obesity; however such controlled substances (Schedules III & IV) are permitted for the treatment of obesity pursuant to KRS 311.597, subject to the following conditions:

Schedule 3 and 4 Anorectics Condition For Use

(A) Prior to initially prescribing any Schedule III or IV anorectic, a physician should:

- (1) Obtain a thorough medical history, including but not limited to:
 - (a) illness;
 - (b) family health;
 - (c) surgery;
 - (d) lifestyle;
 - (e) medications;
 - (f) eating habits;
 - (g) exercise;
 - (h) substance abuse;
 - (i) weight gain and loss;
 - (j) menstruation and pregnancy; and
 - (k) psychosis and depression.
- (2) Perform a complete physician examination including but not limited to:
 - (a) CBC;
 - (b) blood glucose;
 - (c) thyroid function test including TSH;
 - (d) lipid profile;
 - (e) serum potassium;
 - (f) liver function test;
 - (g) kidney function test;
 - (h) pulse;
 - (i) blood pressure;
 - (j) weight;
 - (k) height;
 - (l) BMI;
 - (m) heart function assessment; and
 - (n) skin condition assessment.
- (3) Determine that the patient is an obese adult who is a proper candidate for weight reduction treatment and that the BMI (body mass index

calculated as the weight in kilograms divided by the height in meters, squared) is 27 or more;

- (4) Evaluate the results of all blood or other lab tests; and
- (5) Provide the patient with a carefully prescribed diet, together with counseling on exercise, behavior modification and other appropriate supportive therapy.
- (6) Terminate use of anorectics if patient does not demonstrate weight loss and does not attempt compliance with exercise and dietary changes, i.e., weight loss of four pounds in the first month of use.

(B) To appropriately use anorectics, the physician should consider the following:

- (1) Whether the patient is currently, or has previously obtained or used anorectics or other controlled substances from one or more practitioners and record the answer;
- (2) Whether the patient has a history of or any tendency toward abuse of drugs including alcohol;
- (3) Whether conditions are present that are recognized as contraindicating the use of anorectics, including but not limited to pregnancy, hypertension or hypersensitivity or idiosyncrasy to anorectics; and
- (4) The drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or distribution to others and the presence of an illicit market for the drug.

(C) A physician should record:

- (1) Findings on the initial history and physical;
- (2) The patient's informed consent;
- (3) For each office visit;
 - (a) weight;
 - (b) blood pressure;
 - (c) pulse;
 - (d) subjective assessment of patient including compliance with the program or recommendations;
 - (e) any side effects noted;
 - (f) dose of each drug prescribed.

(4) The patient's BMI every three months;

(5) Medical justification for long term use (greater than three months).

(D) A physician should not initiate or continue prescribing a Schedule III or IV anorectic drug if:

- (1) The patient has a BMI less than 27 unless the BMI is between 25 and 27, **and** the patient has a co-morbidity, including but not limited to:
 - (a) diabetes mellitus;

- (b) hypertension;
 - (c) dyslipidemia; or
 - (d) cardiovascular disease.
- (2) The patient is pregnant or lactating;
 - (3) The patient has engaged in excessive use, misuse or abuse of the anorectic or has otherwise consumed or disposed of the anorectics or any other controlled substance other than in strict compliance with the directions and indications for use given by the physician;
 - (4) An established physician/patient relationship does not exist.

Adopted: December 18, 1996